During a telephone interview, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-26 and 31-36. Applicants affirm this election. Applicants reserve the right to prosecute the Group II claims 27-30 in a divisional application. Claims 27-30 have been canceled from the above-referenced patent application without prejudice.

Rejections

35 U.S.C. §112

Claims 1-26 and 31-36 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action asserts that it is unclear what the term "substantially diagonally to the longitudinal axis" means. Applicants has amended claim 1. "Substantially" was only meant as a qualifier for the term "parallel" and not for the term "diagonal".

The Office Action asserts that it is unclear what the difference is between the terms "rigid-rod" and "semi-rigid rod".

Applicants traverse the rejection. Applicants assert that "rigid rod" and "semi-rigid-rod" are terms of art commonly used in the industry to describe a particular structural class of polymeric materials. See, for instance, E. Hall, C. K. Ober, R.A. Gaudiana and E. Kolb, "Melt Diffusion in Liquid Crystalline Polymers: Rigid Rod vs. Semi-Rigid Rod Model Systems", 53rd Annu. Tech. Conf. - Soc. Plast. Eng., 2, 1950-4, 1995. See also US 5302334, US 6107976, US 5788888, US 6025439, US5998550, US 6242063, and so forth.

The Office Action asserts that it is unclear what the term "semi-compliant" means with respect to a standard.

Applicants traverse the rejection. Applicants submit that "semi-compliant" is a term of art understood by one of ordinary skill in the art. Applicants have given direction as to what polymers may be semi-compliant as several examples of semi-compliant balloon materials have been given on page 5, lines 4-7 of the present specification including "polyamide-polyester block copolymers, namely the polyamide/polyether/polyesters PEBAX® 6333, 7033 and 7233; also polyester-polyether block copolymer such as ARNITEL® 540." The exemplified materials

clearly support the recitation of semi-compliant materials.

Examples of semi-compliant materials are discussed in US 6231543, US 6171278, US 6168617, US 6156053, US 6152944, US 6146356, US 6132450, US 6120534, US 5951941, US 5830,182, US 5658311, US 5645789, US 5556383, and so forth.

The Office Action asserts that it is unclear what the limitation "orientation of the microfibers relative to the longitudinal axis of the balloon changes through the balloon material in a direction transverse to said longitudinal axis" means.

Claim 26 has been amended to clarify what is meant. Applicants assert that the orientation of the balloon fibers in a direction transverse to the longitudinal axis does not have to be the same for all of the fibers. In other words, the angle at which the fibrils are oriented to the longitudinal axis may vary. Applicants believe that the amendment to claim 26 clarifies this statement.

The Office Action asserts that it is unclear what the term "cores" means. Applicants submit that the cores are individual fiber components. See US 5389314 referred to on page 6, lines 14-18 of the present specification. Claims 15 and 16 have been amended.

The Office Action asserts that it is unclear what the claim limitation "operatively adhering" means.

Applicants traverse the rejection. It is clearly described in the specification of the above-referenced patent application as to what is meant by the term "operatively adhering". For example, adhering or adhesion is described on page 6, lines 27-30 and page 7, lines 1-2 where it is stated that "[i]n selecting appropriate materials for the fibrils of cores 30 and matrix 32 it is important to select materials which provide adequate adhesion to one another. ***If adhesion is insufficient between the cores 30 and the surrounding matrix 32 longitudinal growth of balloon 20 will not be restricted as the more expansive matrix material will slip past the individual cores."*** Operative is a term synonymous with function or perform. The adhesion as described is therefore adequate for operation of the balloon. Applicants submit that one of ordinary skill in the art does not require values in order to understand the level of adhesion. Providing that this requirement is met, it is irrelevant what the value is.

The Office Action asserts that it is unclear how the matrix component can be 10 to 12 microns in diameter unless it is actually the fibril component.

Claim 35 has been amended. It is the fibril component which can be 10 to 12 microns. See page 9, lines 1-3.

Based on the foregoing arguments and amendments, Applicants respectfully request withdrawal of the 35 U.S.C. §112 rejections.

35 U.S.C. §103

Claims 1-8, 12-14, 19-26 and 31-36 have been rejected as being unpatentable over Jorgensen (US 5,647,848) in view of Zdrahala (US 5,156,785).

Jorgensen, US 5,647,848

Jorgensen, US 5647848 describes a dilation balloon for securement to a catheter which includes an elastomeric skin having a constraining structure affixed thereto. The constraining structure allows radial expansion between an uninflated diameter D_{defL} and an inflated diameter D_{infL}. The constraining structure is affixed to skin. Preferably, the structure is embedded or otherwise affixed to elastomeric skin. See col. 3, lines 34-37. Claim 1 refers to the structure being affixed to the elastomeric skin. The constraining structure allows unrestrained expansion of the balloon from D_{defL} to D_{infL} but effectively restrains the balloon from undergoing any radial expansion beyond D_{infL}. The constraining structure is preferably formed of helically extending fibers. In turn, these fibers are preferably formed of bundles of continuous monofilaments. Monofilaments, as defined in *Webster's II, New Riverside Dictionary*, Revised Edition, Houghton Mifflin Company, 1996, page46, are referred to as "[A] a single strand of untwisted synthetic fiber used esp. for fishing line." As can be seen from Figs. 2 and 3, the structure formed is shown as being similar to a net-like structure.

In the balloons of the present invention, in contrast, the fibrils are mixed with the matrix material in a molten state. Thus, the fibrils are dispersed throughout the matrix material, and do not form a monofilament structure.

Zdrahala, US 5,156,785

Zdhrahala, US 5156785 describes extruded catheters and other flexible plastic tubing manufactured with improved rotational and/or longitudinal stiffness, compared with

catheters made of more conventional plastics. A tubing of liquid crystal polymer plastic-containing material may be extruded through a tube extrusion die while rotating the inner and outer die walls to provide circumferential sheat to the extruded tube. The liquid crystal polymer is oriented in a helical manner to provide improved properties including greater rotational stiffness.

If desired, tubing may be extruded with no relative rotation between the orifice and the mandrel, but with stretching imposed by an orienting apparatus, with the result that the fibrils of such tubing are generally parallel to the tubing axis. Such a structure tends to have relatively high longitudinal stiffness, but such fibrils make little contribution to the rotational stiffness, so that such a structure will have a rotational stiffness that approximates that of the particular structural plastic matrix used. With high rotation, the helically disposed fibrils exhibit a relatively high angle to the tubing axis, to provide tubing which has increased rotational stiffness. See col. 7, lines 67-68 and col. 8, lines 1-11.

Zdrahala describes tubing formed from liquid crystal polymer plastic-containing material. However, Zdrahala does not teach that these compositions may be employed in dilation balloons, only catheter tubing.

Jorgensen describes a balloon formed from an elastomeric skin further having a constraining structure affixed to an elastomeric skin to limit expansion of the balloon body. Preferably, the structure is embedded or otherwise affixed to the elastomeric skin. See col. 3, lines 34-39. The constraining structure is formed of helically extending fibers formed of bundles of continuous monofilaments. Jorgensen describes the use of LCP only in the ***constraining structure*** but not in the elastomeric skin.

There is no suggestion in the combination of these references that a dilation balloon could be made without the ***constraining structure*** to limit expansion of the balloon body as taught by Jorgensen. Thus, Applicants submit that one of ordinary skill in the art would not be motivated to make a dilation balloon without the constraining structure.

The present invention employs a polymeric matrix component ***mixed*** with a fibril component to make a balloon having no constraining structure. Independent claims 1 and 31 have been amended to clarify this feature. This is described on page 7 of the present specification. Claims 2-7, 12-14 and 19-26 depend from claim 1 and claims 32-36 depend from

claim 31.

Based on the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of claims 1-8, 12-14, 19-26 and 31-36.

Claims 9-10 have been rejected under 35 U.S.C. §103(a) as being unpatentable as applied to claims 1-8, 12-14, 19-26 and 31-36 above, and further in view of Cozewith et al. The Office Action asserts that Jorgensen fails to teach the use of a compatibilizer in the blend, and that Zdrahala fails to teach that any block copolymer in the blend is specifically a compatibilizer. The Office Action further asserts that Cozewith et al. discloses that it is well known in the art to use block copolymers as compatibilizers for emulsifying polymer/polymer blends (col. 1, lines 15-25) and that a block copolymer compatibilizer is composed of two or more polymer molecules of different chemical composition covalently bonded in an end-to-end fashion (col. 1, lines 15-35).

Applicants submit that claims 9-10 are dependent from claim 1 and are patentable for at least the reasons that claim 1 is patentable. Further to claims 9 and 10, Cozewith et al. make no suggestion that such block copolymers might find use as compatibilizers in compositions used in the manufacture of dilation balloons. Thus, Applicants submit that there would be no motivation to combine Cozewith et al. with Jorgensen.

Furthermore, as described above, Jorgensen teaches a balloon with a ***constraining structure*** affixed to an elastomeric skin. There is nothing to suggest in combining Cozewith et al. with Jorgensen and Zdrahala, that would lead one of ordinary skill in the art to composition having a block copolymer compatibilizer for use in a dilatation balloon without a ***constraining structure*** to limit expansion of the balloon. In fact, to the contrary, it would be more reasonable for one of ordinary skill in the art to believe that the addition of a compatibilizer to a balloon composition would be more likely to require the use of a constraining structure to limit expansion as taught by Jorgensen.

Double Patenting

Claim 11 has been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of commonly assigned U.S. Patent No. 6,242,063 in view of Zdrahala.

Applicants are submitting a terminal disclaimer herewith.

Claims 15-18 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of commonly assigned U.S. Patent No. 6,284,333 in view of Zdrahala.

Applicants are submitting a terminal disclaimer herewith.

Applicants respectfully request withdrawal of the rejection of claim 11 and claims 15-18 under the doctrine of obviousness-type double patenting.

CONCLUSION

Claims 1-26 and 31-36 are pending in the application. Based on the foregoing arguments and amendments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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MARKED UP VERSION TO SHOW CHANGES MADE

In the Claims

1. (Amended) A dimensionally stable polymer balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a polymer fibril component mixèd [distributed] in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel, or diagonally to the longitudinal axis of the balloon.

26. (Amended) [The] A dimensionally stable polymer balloon [of claim 1] having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a polymer fibril component having micro-fibers, said fibril component mixed in the polymer matrix component, wherein the orientation of the micro-fibers relative to the longitudinal axis of the balloon varies [changes through] throughout the balloon material in a direction transverse to said longitudinal axis.

31. (Amended) An inflatable medical balloon having [a determined pre-inflation length, restricted longitudinal or radial expansion characteristics,] a circumference and a longitudinal axis comprising:

a matrix material, said matrix material characterized as being semi-compliant;

and having a plurality of individual fiber cores mixed therethrough, said cores being evenly distributed about the circumference of the balloon and being composed of one or more materials which are characterized as being stronger than the matrix material and having a bulk elongation less than the matrix material when the one or more materials are oriented in the direction of the longitudinal axis, and the matrix material and the core material operatively adhering to one another.

35. (Amended) The medical balloon of claim 31, wherein the [matrix] fibril component is between about 10 microns and about 12 microns in diameter.